K052677

OCT 1 2 2005

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes Universal Locking Trochanter Stabilization Plate (ULTSP)

Classification: Class II, §888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Predicate Devices: Synthes Trochanter Stabilization Plate (TSP) for DHS

Device Description: The Synthes ULTSP for DHS® and LCP DHHS fits over the sideplate of the Synthes DHS and LCP® DHHS. The ULTSP screw holes line up with the most proximal screw holes of the DHS and LCP DHHS sideplate and accept 4.5 mm cortex screws used for femoral shaft fixation. Slots accommodate both the DHS lag screw or the LCP DHHS Helix Blade and a parallel anti-rotational screw. The screw slot for the anti-rotational screw accepts a 6.5 mm cancellous bone screw or 6.5 mm, 7.0 mm or 7.3 mm cannulated screw. The proximal extension of the plate resides along the lateral side of the greater trochanter. The proximal locking holes of the ULTSP accept 3.5 mm locking screws and/or k-wires, cables, or sutures up to 2.0 mm in diameter.

Intended Use: The Synthes Universal Locking Trochanter Stabilization Plate for DHS® or LCP DHHS is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw (DHS®) or the LCP Dynamic Helical Hip System (DHHS) side plates with four or more holes.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2005

Sheri L. Musgnung
Sr. Regulatory Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K052677
Trade/Device Name: Synthes (USA) Universal Locking Trochanter Stabilization Plate (ULTSP)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: September 27, 2005
Received: September 29, 2005

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 **Indications for Use**

510(k) Number (if known): K052677

Device Name: Synthes (USA) Universal Locking Trochanter Stabilization Plate (ULTSP)

INDICATIONS FOR USE:

The Synthes Universal Locking Trochanter Stabilization Plate for DHS® or LCP® DHHS is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw (DHS®) or the LCP® Dynamic Helical Hip System (DHHS) sideplates with four or more holes.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052677